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Document Processing Desk - 6(a)(2)
Office of Pesticide Programs
Document Processing Room S-4900
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Subject: Active Ingredient(s): Glyphosate
Product(s): specific brand not determined
EPA Registration Number(s): not determined
Information which may be required under Section 6(a)(2) of FIFRA

To Whom It May Concern:

Monsanto submits the following allegation by a Veterinarian that glyphosate has played a role in the calf fatalities observed by a cattle rancher in Saskatchewan, Canada. As indicated in EPA guidance, Monsanto's submission of this claim does not suggest that any of the reported information is factual or accurate. 62 Fed. Reg. 49369, 49736 (Sep. 19, 1997).

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Calves (approximately 10 months of age) were on self-feed pellets up until December 27th, 2016. Pellets were lentil screenings and had been used in both 2015 and 2016. Feed ratio was changed to barley chop on December 28th, 2016. Flax straw bedding has been used, the source being a stand of flax treated with glyphosate pre-harvest. The flax straw has been processed and broken up into small pieces. Calves were noted to have eaten some of this material. Shortly after the feed change multiple (approximately 40) calves became ill and a total of 11 calves died over the course of two days despite treatment (specifics not provided). A veterinarian involved in the case indicated a belief that glyphosate may be responsible for the deaths. Flax and lentil screening samples were available for analysis and were recently sent to a laboratory in Canada to examine for glyphosate and AMPA.

The laboratory reported flax values as 97 ppb AMPA, 361 ppb glyphosate, total 488 ppb. Lentil pellets had 111 ppb AMPA and 2838 ppb glyphosate, total of 2949 ppb. AMPA is generally treated as equivalent to glyphosate in regards to residue limits. Comparison with allowable residues indicates the following:

Flax	0.488 ppm
Lentil pellet	2.949 ppm
Tolerance- Animal feed, Non-Grass	400 ppm
Tolerance- Grass fodder, forage, and hay (Gp 18)	300 ppm
Tolerance- Cereal, forage, fodder and straw (Gp 16)	100 ppm

A toxicity study of MON 0139 (aqueous glyphosate IPA solution) in cattle was conducted by Monsanto¹. Cattle were dosed for 7 consecutive days at several dose levels. The NOEL (no effect level) was

¹ Rowe, L.D. et al., The Subacute Toxicity of the Isopropylamine Salt of Glyphosate (MON 0139) in Female Cattle, USDA Veterinary Toxicology and Entomology Research Laboratory, Study 82002 (Monsanto Study VT-82-003), 1987.

determined to be 0.54 g MON 0319/kg body weight/day, or 50 g glyphosate acid/day. In order for a cow to be exposed to 50 g glyphosate acid per day (which showed no effects in the study) they would need to consume 100,000 kg flax straw or 17,000 kg lentil pellets per day. Further, although the veterinarian has speculated that adverse effects may be the result of the binding of essential minerals, there is no evidence to support this hypothesis and, in fact, glyphosate concentrations are far too low (on a molar basis) to possibly chelate the levels of minerals found routinely in animal feed.

Monsanto does not believe that glyphosate products are responsible for the calf fatalities reported herein.

If there are questions about this report, please contact James Nyangulu at (202) 383-2851 or by email at james.m.nyangulu@monsanto.com, or me directly at (314) 694-1538 or by email at simone.scifert-higgins@monsanto.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Simone Higgins", with a stylized flourish at the end.

Simone Seifert-Higgins, Ph.D.
Regulatory Affairs Manager
Monsanto Company
US Chemical Regulatory Affairs